BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

OCT 1992 ELLECTUAL PROPERTY ORGANIZATION
International Bureau

285-32614

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 5/00

A1

(11) International Publication Number: WO 92/17221

(43) International Publication Date: 15 October 1992 (15.10.92)

(21) International Application Number: PCT/US92/01550

(22) International Filing Date: 28 February 1992 (28.02.92)

(30) Priority data:
677,724 29 March 1991 (29.03.91) US

(71) Applicant: BOSTON SCIENTIFIC CORPORATION [US/US]; 480 Pleasant Street, Watertown, MA 02172 (US).

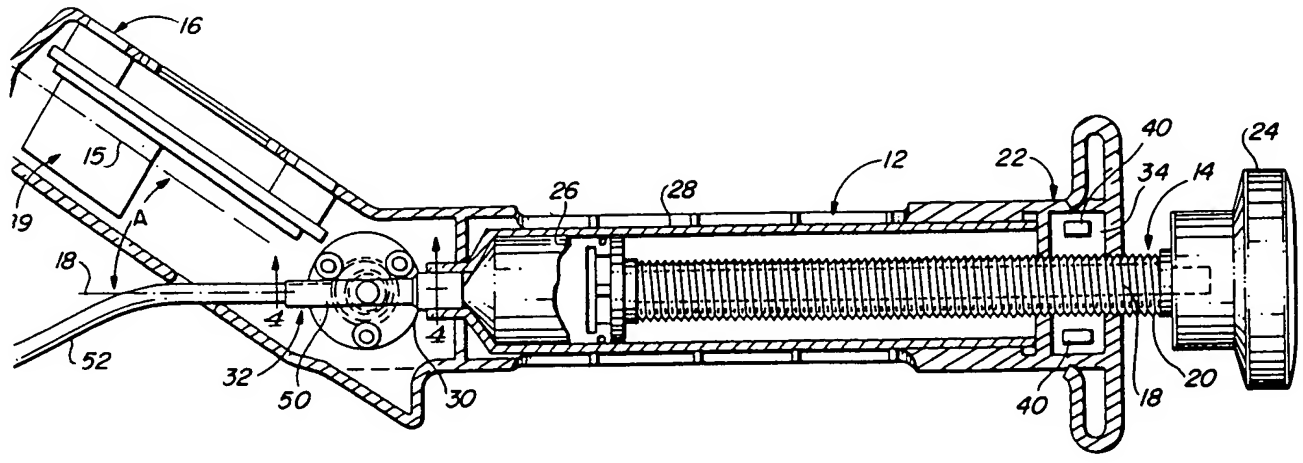
(72) Inventor: PHELPS, David ; 50 Golden Ball Rd., Weston, MA 02193 (US).

(74) Agent: HALGREN, Donald; Boston Scientific Corporation, 480 Pleasant Street, Watertown, MA 02172 (US).

(81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), SE (European patent).

Published
With international search report.

(54) Title: DIGITAL INFLATION DEVICE



(57) Abstract

A manually carriable digital inflation device for monitoring pressure in an angioplasty balloon catheter in a patient having an elongated main housing (12) which has a pressure generating piston (26) and cylinder (28) adapted through a pressure sensor (32), to digitally display (16) the pressure, elapsed time or duration of the pressure generated, and the number of cycles of pressure generated and communicated to a balloon catheter. The distal display panel (16) receives this information through a proper circuit connected to the sensor. The display panel (16) is canted at an angle with respect to the elongated housing (12) to make the display easier to read and respond.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MC	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	RU	Russian Federation
CG	Congo	KP	Democratic People's Republic of Korea	SD	Sudan
CH	Switzerland			SE	Sweden
CI	Côte d'Ivoire	KR	Republic of Korea	SN	Senegal
CM	Cameroon	LI	Liechtenstein	SU	Soviet Union
CS	Czechoslovakia	LK	Sri Lanka	TD	Chad
DE	Germany	LU	Luxembourg	TG	Togo
DK	Denmark	MC	Monaco	US	United States of America

DIGITAL INFLATION DEVICE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to apparatus for performing angioplasty procedures opening up occluded blood vessels and more particularly to an inflation device for dispensing inflatable fluid into a balloon catheter.

2. Prior Art

Proper Inflation and Deflation of Balloons in Angioplasty Balloon Catheters is an Absolute Necessity during life threatening angioplasty procedures. The operating physician has to know the pressure at which the balloon is being inflated, and often has to leave them inflated for a very definite period of time.

U.S. Patent 4,723,938 to Goodin et al discloses a single plunger inflation device for inflating a balloon catheter.

U.S. Patent 4,815,313 to Beard shows a calibration reference device for monitoring pressures developed by a hypodermic syringe. A microprocessor is arranged to digitally display the pressure developed within the syringe barrel as the physician moves the plunger of the syringe. U.S. Patent

4,370,982 to Reilly shows an apparatus and a method for controlling the pressure of fluid injected into a catheter. A controlled device is included to permit a rapid increase or decrease in the fluid pressure to facilitate maintenance of a particular pressure by a manual means with an analog device.

European Patent Application publication no. 0 290 770 to Hajianpour, shows a pressure sensor device to be connected with a needle or catheter using a diaphragm which is adapted to sense the pressure within a needle or syringe. A microprocessor is connected to the diaphragm which in turn feeds a series of LED lights to indicate a particular pressure range reached by the balloon attached to the sensing mechanism. Lights, are of different colors to indicate a safe or unsafe pressure region.

European Patent Application publication no. 0 396 353 of Shockey discloses a housing mounted digital display on an inflation/deflation device, which fails however to develop a full display of necessary data in a user friendly arrangement.

It is an object of the present invention to overcome the shortcomings of the prior art. It is a further object of the present invention to provide readily readable digitized information to our physician operating angioplasty catheter without any guesswork or interpretation of the results being reviewed.

BRIEF SUMMARY OF THE INVENTION

The present invention comprises a hand held pressure generated monitor utilizing digital read out of a plurality of functions related to a pressurized angioplasty balloon catheter.

The present invention is a fully self-contained pressure generator and monitor with means for attachment to a connector junction on the proximal end of a angioplasty catheter arrangement. The digital inflation monitor comprises a generally longitudinal housing having a plunger mechanism at one end thereof. The housing has an angularly displaced readout display disposed at the other end thereof. The angular relationship of one end of the housing to the other permits ease of display for the operating physician. The elongated housing has a proximal end through which an axially displaceable plunger rod is disposed. The plunger rod itself has a knob on its proximalmost end extending out of the proximal end of the housing. The rod is a threaded shaft going through an adjustment nut in the housing. The plunger rod has a sealed piston at its distalmost end which slides within a tubular member to generate the desired pressure within the balloon catheter. The distalmost end of the tubular member is fed through a luer connector, which may connect via a high pressure

tube fitting, to a connector at the proximal end of an angioplasty balloon catheter assembly. A sensor is arranged within the luer connector, to pick up particular pressure signals generated therein. The sensor is electrically connected to a printed circuit board containing an analog to digital converter and a microprocessor. The analog to digit converter and the microprocessor are both in the electrical communication with a liquid crystal display panel which keeps track of the pressure on a real time basis, it keeps time in minutes and seconds of the pressure as established within the balloon, and it also keeps digital display of the number of inflations the balloon has undergone within the angioplasty balloon catheter assembly.

The manually held digital inflation device for monitoring pressure in an angioplasty balloon catheter in a patient, of the present invention comprises: a main housing having pressure generation means disposed through a proximal end thereof; a fluid conduit adaptable for fluid communication with an angioplasty balloon catheter; a pressure sensor in communication with the fluid conduit, for the receipt of fluid pressure characteristics within the conduit; and a digital display of the fluid pressure characteristics at a digital display panel, through a circuit means arranged between the sensor and the display panel, to conveniently show the operator of the device the critical pressure characteristics generated in

a balloon catheter associated with the device the panel digitally displays the pressure of fluid in the fluid conduit, the time of duration of the pressure in the fluid conduit and the number of pressure cycles generated within the fluid conduit by the pressure generating means in said device.

The present invention also includes the digital display panel being disposed in a display housing at the proximal end of the main housing, said display housing being arranged at an acute angle with respect to the main housing, to facilitate operator viewing of the panel.

The manually held digital inflation device includes a switch arranged with the circuit to start and stop and reset the display panel.

A releasable engaging mechanism is adapted to hold or selectively release said pressure generator means so as to effect the pressure in a balloon catheter pursuant to a display panel readout.

The pressure generator means comprises a piston on a shaft and a cylinder arrangement, and the releasable engaging mechanism comprises a partially threaded split nut which is contractable and separable from said the shaft so as to engage or release the shaft to permit the effectuation of pressure within the cylinder

arrangement.

The method for monitoring pressure applied to an angioplasty balloon catheter now comprising the steps of providing a pressure generating piston and cylinder arrangement in an elongated housing with a fluid conduit from the cylinder, attachable to a balloon catheter; arranging a pressure sensor in fluid communication with the fluid conduit from the cylinder; interconnecting the pressure sensor through a controllable circuit which is displayable as digitized information on a display panel arranged at one end of the elongated housing;

displaying important pressure, elapsed duration of pressure and number of pressure cycles of the pressure generating piston and cylinder arrangement sensed at the fluid conduit by said sensor and converted into a digital display by the circuit, for easily controlling the pressure applied to any balloon catheter attached to the device.

BRIEF DESCRIPTION OF THE DRAWINGS

The objects and advantages of the present invention will become more apparent when viewed in conjunction with the following drawings in which:

Figure 1 is a isometric view of the digital inflation device constructed according to the principles of the present

invention;

Figure 2 is a side elevational view in section of the digital inflation device;

Figure 3 is a side view of one-half of a locking nut adapted within the housing on the proximal end of the elongated plunger rod;

Figure 4 is a view taken along the lines IV - IV of Figure 2; and

Figure 5 is a block diagram of the circuitry for the digital inflation device herewith.

Description of The Preferred Embodiments

Referring now to the drawings in detail, and particularly to figure 1, there is shown a digital inflation device 10 which comprises a fully self contained hand held pressure monitor utilizable in conjunction with balloon catheter angioplasty devices, not shown.

The digital inflation device 10 comprises a generally elongated main housing 12 having a plunger mechanism 14 thereat. A readout display housing 16 has a longitudinal axis 15 shown in figure 2 which is angularly disposed at the other end of the

main housing 12, at an angle "A" of about 20 degrees to about 60 degrees with respect to the longitudinal axis 18 of the main housing 12.

The plunger mechanism 14 comprises an elongated threaded shaft 20 rotatably disposed through an adjustment nut 22 as partially shown in figures 2 and 3. The threaded shaft 20 has a knob 24 on its proximalmost end, and a piston 26 attached to its distalmost end. The piston 26 and its attendant threaded shaft 20 are slidably disposed in a cylinder or tubular pressure member 28. The pressure member 28 has an opening 30 at its distalmost end, which is in fluid communication with a sensor conduit 32, as shown in figures 2 and 4.

The fluid pressure within the pressure member 28 is generated in a known way, by advancing the piston 26 therein to compress any fluid in the pressure member 28. The threaded shaft 20 may be rotatively advanced (or retracted) through the adjustment nut 22. The half of the adjustment nut 22 not shown in figure 2 comprises a U-shaped member 32 having a smooth semi-annular surface which is in close proximity to the threaded shaft 20. The half of the adjustment nut 22 which is shown in figure 2 also comprises a U-shaped member 34 also having a semi-annular surface 36, but also having a plurality of semi-circular threads 38 disposed thereacross, as shown in figure 3. A spring, not shown, is placed between the threaded member 34 and the inside of the split housing 12, in which half the threaded member 34 mates. The smooth (non-engaging) member, not shown in

the other half of the split housing 12, and together surround the threaded shaft 20 therebetween. The U-shaped members mate together by projections 40, and receiving openings on the other member, not shown. A button 42, shown in figure 1, when pushed, pushes the smooth U-shaped member which has room to move and allow shaft 20 to still move as well, displacing the threads 38 on the other half of adjustment nut 22 from engagement with the threads in the shaft 20, permitting rapid advancement or retraction of the piston 26 in the tubular member 28.

The sensor fluid conduit 32 comprises a tubular shaft 50 which extends between the opening 30 in the downstream end of the pressure member 28, and a high pressure tube 52, shown in figure 2. The high pressure tube 52 is in fluid communication with a balloon angioplasty catheter assembly, not shown, for supplying and withdrawing pressurized fluid from the balloon on the catheter.

The sensor fluid conduit 32 is secured to a printed circuit board 56, and a back-up plate 58. The shaft 50 has an opening 60 which exposes any pressured fluid within the shaft 50 to a pressure monitor 62 disposed on the printed circuit board 56. The pressure monitor 62, shown schematically in figure 5, is connected, through a circuit 64 to an analogue to digital converter 66. The converter 66 is linked to a microprocessor 68 through a control line 70. The microprocessor 68 has memory capabilities to store procedure data and is outputable through a standard computer port 69 disposed through the housing 12, and

is attachable to a strip recorder or other computer, not shown, to further facilitate medical treatment of a patient being treated. An audible beeper 72 is in electrical communication with the micorprocessor 68, to an on-off switch 74 and a start-stop switch 76. The microprocessor 68 and the converter 66 are each connected to a display panel 78 having liquid crystal read-out display characters which provide the pressure of the fluid within the high pressure tube 52(as read by the pressure monitor) to give all of the critically important information, which is the pressure reading 80 of an attached balloon catheter, the time lapsed during which that pressure is maintained, by a time display means 82, and a counter which tracks the number of times the pressure has been reduced and repressurized, as an inflation counter display means 84. The microprocessor 68 also provides a back-light means 86 for liquid crystal display panel 78, all of which circuitry is powered by a battery 89.

Thus an operator of such a digital inflation device 10 attaches the high pressure tube 52 to a connector, not shown, which is in communication with a balloon feed lumen in a balloon catheter after the catheter has been properly emplaced within a stenotic lesion of a patient. By turning the proper circuitry on through the on switch 74, the physician is able to begin to advance and hence create pressure within the cylinder/pressure member 28 and hence a balloon catheter, not shown, which would be thereattached. The pressure monitor 62 supplies analogue

signals through a proper circuit 64 to a proper analogue to digital converter 66 which transmits the digital signal to a proper microprocessor 68.

The display panel 78 then flashes-out in a digital format the measured pressure, time and number of inflations at the liquid crystal display. The beeper 72 may be programmed within the microprocessor 68 to audibly alert the physician once a particular pressure, time or number of inflation count has been reached.

The physical configuration of the display canted at an angle with respect to the main housing 12 of the digital inflatino device 10 permits ease of reading the display panel 78 and good access to the switch means 74 and 76 therewith.

I claim:

1. A manually held self-contained digital inflation device for displaying in a digital format the pressure, time and number of inflations of a balloon angioplasty catheter, comprising:

a main housing having a pressure generating chamber therewithin and a displacable piston for effectuating pressure within that chamber;

a fluid pressure conduit in fluid communication with said chamber, said fluid pressure conduit connectable to a balloon catheter;

a pressure sensor in fluid communication with said fluid pressure conduit to signal through circuit means, a display panel to display important pressure, elapsed time of pressure maintained and number of pressure cycles information in a digital manner to an operator of said device.

2. A manually held digital inflation device as recited in claim 1, wherein said main housing has a proximal and a distal end, said distal end having a display housing angularly arranged thereon so as to facilitate operation of said device.

3. A manually held digital inflation device as recited in claim 1, wherein said display housing has a longitudinal axis disposed at an angle of about 20 to about 60 degrees from the longitudinal axis of said main housing.

4. A manually held digital inflation device for monitoring pressure in an angioplasty balloon catheter in a patient, comprising:

a main housing having pressure generation means disposed through a proximal end thereof;

a fluid conduit adaptable for fluid communication with an angioplasty balloon catheter;

a pressure sensor in communication with said fluid conduit, for the receipt of fluid pressure characteristics within said conduit; and

a digital display of said fluid pressure characteristics at a digital display panel, through a circuit means arranged between said sensor and said display panel, to conveniently show the operator of said device the critical pressure characteristics generated in a balloon catheter associated with said device said panel digitally displays the pressure of fluid in said fluid conduit, the time of duration of said pressure in said fluid conduit and the number of pressure cycles generated within said fluid conduit by said pressure generating means in said device.

5. A manually held digital inflation device as recited in claim 4, wherein said digital display panel is disposed in a display housing at the proximal end of said main housing, said display housing being arranged at an acute angle with respect to said main housing, to faciliate operator viewing of said panel.

6. A manually held digital inflation device as recited in claim 5, including a switching means arranged with said circuit means to start and stop and reset said display panel.

7. A manually held digital inflation device as recited in claim 6, including a releasable engaging means adapted to hold or selectively release said pressure generation means so as to effect the pressure in a balloon catheter pursuant to a display panel readout.

8. A manually held digital inflation device as recited in claim 7 wherein said pressure generation means comprises a piston on a shaft and a cylinder arrangement, and said releasable engaging means comprises a partially threaded split nut which is contractable and separable from said shaft so as to engage or release said shaft to permit the effectuation of pressure within said cylinder arrangement.

9. A method for monitoring by a manually carried device, the

pressure applied to an angioplasty balloon catheter comprising the steps of:

providing a pressure generating piston and cylinder arrangement in an elongated housing with a fluid conduit from said cylinder, attachable to a balloon catheter;

arranging a pressure sensor in fluid communication with said fluid conduit from said cylinder;

interconnecting said pressure sensor through a controllable circuit means which is displayable as digitized information on a display panel arranged at one end of said elongated housing;

displaying important pressure, elapsed duration of pressure and number of pressure cycles of said pressure generating piston and cylinder arrangement sensed at said fluid conduit by said sensor and converted into a digital display by said circuit, for easily controlling the pressure applied to any balloon catheter attached to said device.

10. A method for monitoring, by a manually carried device, the pressure applied to an angioplasty balloon catheter as recited in claim 9, including the step of:

signaling by an audible alarm energized by said circuit, when said pressure sensor reports to said circuit a predetermined pressure, time or quantity of pressure cycles.

11. A method for monitoring, by a manually carried device, the pressure applied to an angioplasty balloon catheter as recited

in claim 10, comprising the step of:

arranging said digital display at an acute angle with respect to the longitudinal axis of said elongated main housing so as to present said display in an easily read manner.

12. A method for monitoring, by a fully self contained manually carried device, the pressure applied to an angioplasty balloon catheter as recited in claim 10, including the step of:

outputing procedure data through said circuit means, to an outside computer device so as to further facilitate medical treatment of a patient.

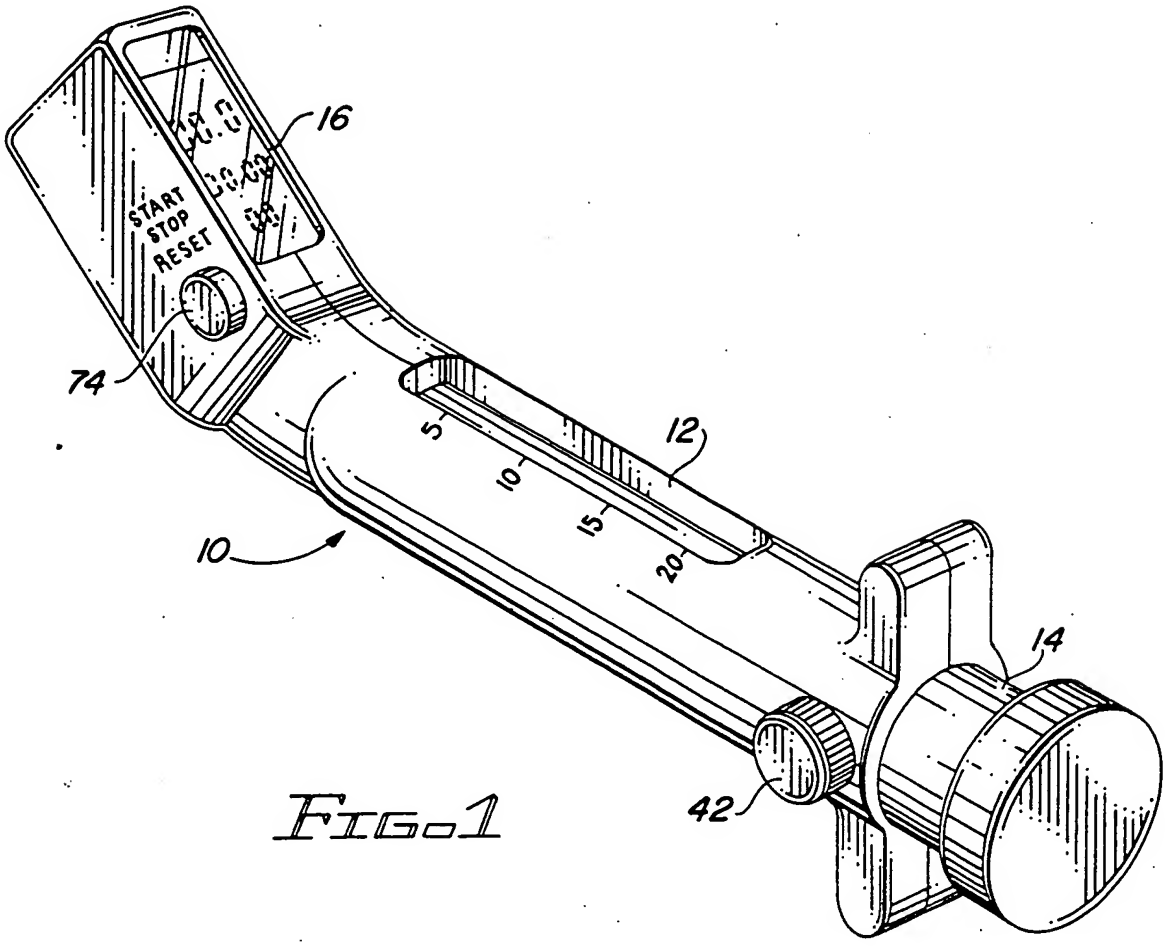


FIG-1

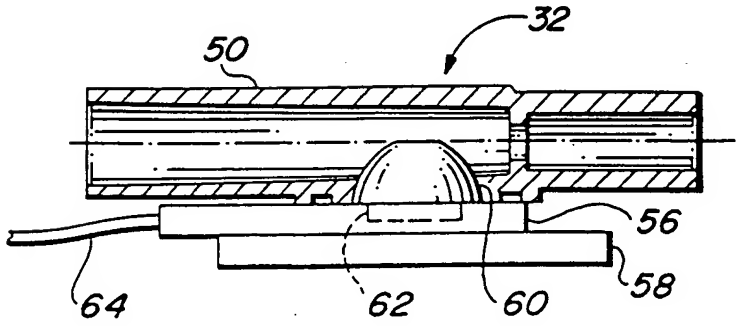


FIG-4

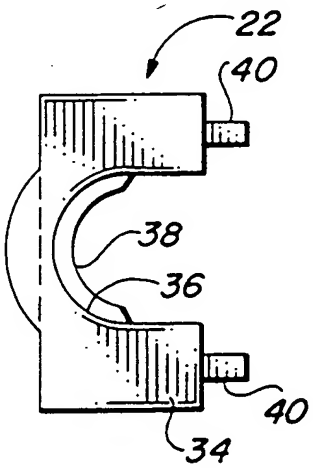


FIG-3

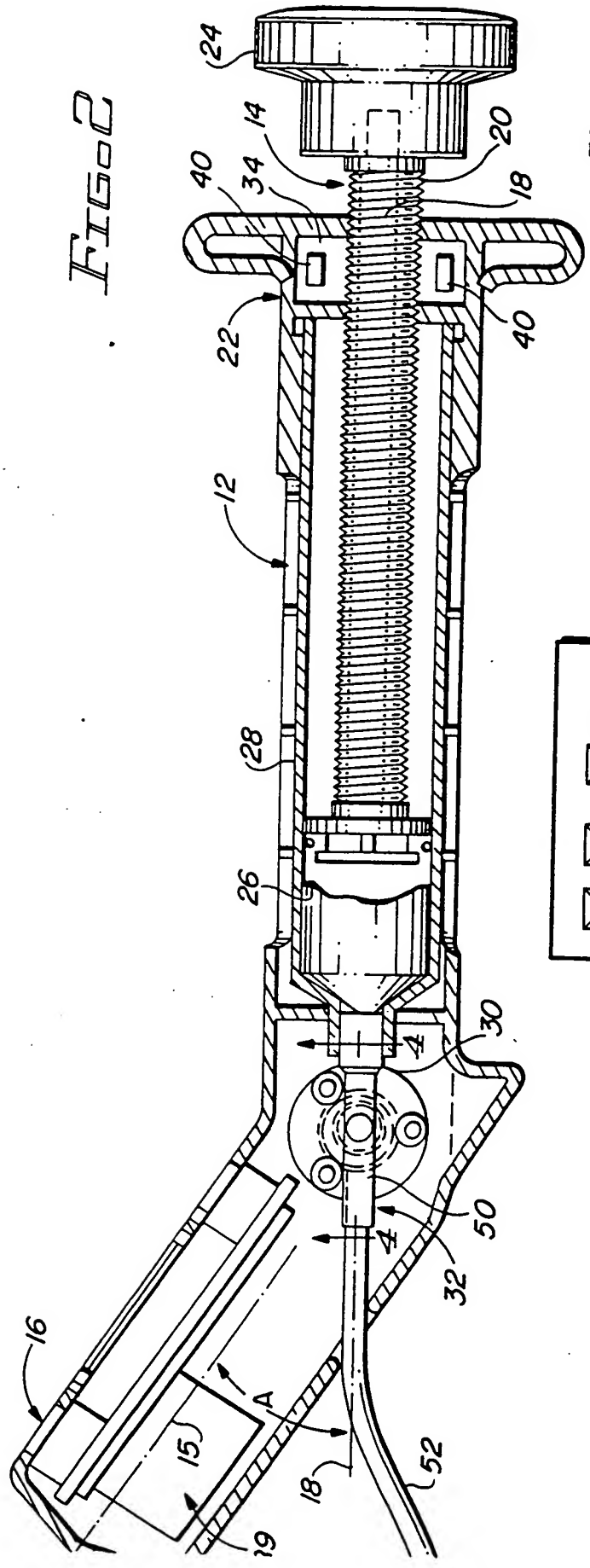

24
14
20
40
34
18
22
40
12
28
26
30
4
4
50
32
16
15
A
18
52
19

Fig-2

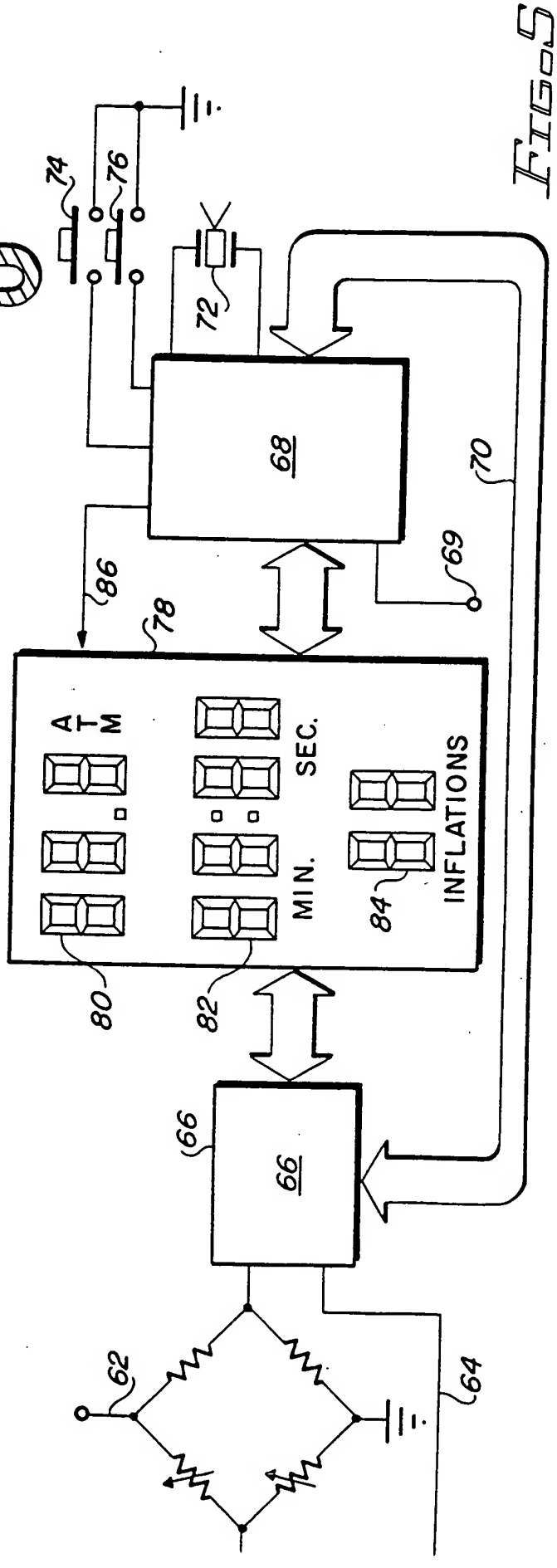

74
76
72
68
70
69
86
78
A
T
M
SEC.
MIN.
INFLATIONS
84
80
82
66
66
62
64

Fig-5

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61M 5/00
US CL :604/100

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/65-67, 97-100, 118, 120-121, 124, 152, 155, 207-211, 224
128/774

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P Y	US, A, 5,021,046 (WALLACE) 04 June 1991, See entire disclosure.	1 2-12
Y,P	US, A, 5,019,041 (ROBINSON ET AL) 28 May 1991, See entire disclosure.	1-12

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be part of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

14 July 1991

Date of mailing of the international search report

17 JUL 1992

Name and mailing address of the ISA/
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. NOT APPLICABLE

Authorized officer

Nga Ho Nguyen

MARK W. BOCKELMAN NGUYEN NGOC-HO
INTERNATIONAL DIVISION

Telephone No. (703) 308-0858